UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF TENNESSEE NASHVILLE DIVISION

UNITED STATES OF AMERICA, ex rel.,)	
STEPHEN MCMULLEN,)	
Plaintiffs,)	CIVIL CASE NO. 3:12-cv-00501
)	JUDGE CAMPBELL
V.)	MAGISTRATE JUDGE GRIFFIN
)	
ASCENSION HEALTH, SEATON)	
CORPORATION (D/B/A BAPTIST)	
HOSPITAL, HICKMAN HEALTH)	
CARE SERVICES INC. (D/B/A)	
HICKMAN COMMUNITY HOSPITAL,)	
and MIDDLE TENNESSEE MEDICAL)	
CENTER, INC.)	
)	
Defendant.)	

UNITED STATES STATEMENT OF INTEREST ON DEFENDANT'S MOTION TO DISMISS AND REPLY IN SUPPORT

On August 20, 2013, Defendants Ascension Health, Seton Corporation (d/b/a Baptist Hospital), Hickman Community Health Care Services (d/b/a Hickman Community Hospital), and Middle Tennessee Medical Center, Inc. (collectively "Defendants") filed a Motion to Dismiss (D.E. 56) and Memorandum in Support (D.E. 57) seeking dismissal of this False Claims Act lawsuit on various grounds. On September 20, 2013, Relator filed his Response in Opposition (D.E. 61). Finally, on October 2, 2013, Defendants filed their Reply in Support of their Motion to Dismiss (D.E. 63). Although the United States has not intervened in this case and is not a formal party, it remains the real party in interest in this action. *See United States ex rel. Eisenstein v. City of New York, New York*, 556 U.S. 928, 930 (2009). The False Claims Act, 31 U.S.C. § 3729 *et seq.*, ("FCA") is the United States' primary tool for redressing false claims

submitted to the government. As such, the statute should be read broadly to reach all fraudulent attempts to cause the government to pay out sums of money. United States v. Neifert-White, 390 U.S. 228, 233 (1968). Thus, the United States has a keen interest in the development of the law in this area and in the correct application of the law in this, and similar, cases.

Accordingly, the United States respectfully submits this Statement of Interest, pursuant to 28 U.S.C. § 517, to provide assistance to the Court in interpreting and applying the FCA on two discrete issues. The United States takes no position on the merits of Relator's claims.

Proper Application of Prior Decisions to Whether a Local Coverage I. **Determination Can Form the Basis of a FCA Cause of Action**

In his Complaint, Relator alleges that Defendants violated one or more Local Coverage Determinations ("LCDs")² concerning the provisioning of ultrasonic vascular imaging. See, e.g., Am. Compl., pp. 4, 6-7 (D.E. 39). In response, Defendants argue that an LCD cannot form the basis of a FCA cause of action because they do not constitute "conditions of payment." See D.E. 57 at 12 – 15. In support of this assertion, Defendants cite two cases, *United States ex rel. Hobbs* v. Medguest Assoc. Inc., 711 F.3d 707 (6th Cir. 2013) and United States v. R.D. Prabhu, 442 F. Supp. 2d 1008 (D. Nev. 2006). See D.E. 57 at 14 – 15; D.E. 63 at 13. Assuming arguendo that a factual basis exists for the application of the LCDs identified by Relator to Defendants,

¹ Although Defendant's Memorandum in Support of its Motion to Dismiss repeatedly refers to fraud and fraudulent schemes, the United States notes that, "[N]o proof of specific intent to defraud is required' for an FCA claim." United States ex rel. Wall v. Circle C Constr., LLC, 697 F.3d 345, 356 (6th Cir. 2012) (quoting 31 U.S.C. § 3729(b)(3) (2006) [now 31 U.S.C. § 3729(b)(1)(B)]).

² LCDs are defined as "a determination by a [Medicare] fiscal intermediary or a carrier . . . respecting whether or not a particular item or service is covered on an intermediary- or carrierwide basis under such parts, in accordance with . . . [42 USCS § 1395v(a)(1)(A)]." 42 USC § 1395ff.

Defendants' reliance on MedQuest and Prabhu to argue that LCDs cannot form the basis of a FCA cause of action is misplaced.³

In *MedQuest*, the United States alleged, *inter alia*, that the defendant had submitted false claims because the physicians it employed to provide direct supervision for contrast testing procedures did not meet the requirements set forth in the local Medicare carrier's Local Medical Review Policy ("LMRP") 4 which applied to the procedures being performed. MedQuest, 711 F.3d at 709. In analyzing the United States FCA claim based on the LMRP's physician supervision requirement, the *MedQuest* court determined that no FCA liability existed because the LMRP's requirements which the United State alleged had been violated were not conditions of payment and thus could not support FCA liability. Id. at 717. Defendants citation to MedQuest, however, ignores that the court engaged in a detailed analysis of the language of the LMRP at issue, before concluding that the physician requirement did "not purport to supplement the reasonable and necessary conditions" of Medicare's regulations and could not underlie an FCA cause of action. *Id.* at 716 - 717. Importantly, in the course of that analysis, the court recognized that the LMRP set forth situations which would result in a denial of payment, but went on to find that the LMRP's physician supervision requirement was not one of those situations. Id. Indeed, MedQuest acknowledged that a section of the LMPR at issue set forth conditions of payment, stating that "payment may be denied" for a number of reasons set forth in the LMRP, including "when the services are performed for screening purposes," and "when the patient's record lacks evidence that the treading physician did not [sic] order the test." Id. The court contrasted these specific instances, which the LMRP stated payment could be denied, with

³ The United States does not take a position on any factual issues in this case, such as what LCD was applicable to Defendants during what time period and whether or not Defendants complied with that LCD. This Statement is limited to the application of MedQuest and Prabhu assuming all of Relator's well-plead allegations to be true at this stage of the proceedings.

⁴ LMRPs were the precursor to LCDs.

the conduct alleged by the Government and concluded that "the implication is the LMRP does not forbid payment when there are regulatory violations like the ones at issues here." *Id.* Contrary to Defendants assertion, the court did not conclude that any violation of the LMRP would not result in a denial of payment. As such, *MedQuest* does not support Defendant's argument that "LCDs are not regulations and do not establish binding conditions of payment actionable under an implied false certification theory." (D.E. 63 at 13). If an LCD which applied to Defendants sets forth conditions under which payment for noninvasive vascular diagnostic services may be denied, that LCD could serve as a "condition of payment" on which to base a FCA cause of action predicated on an implied certification theory. The *MedQuest* court clearly recognized this possibility, noting that "other Medicare regulations applied to MedQuest," apart from 42 C.F.R. § 410.32, and considered CIGNA's local policies to be "[a]mong these other requirements." *Id.*

Defendants also cite *Prabhu* for their argument that violations of an LCD cannot create FCA liability. Defendants state that *Prabhu* found that "claims that did not comply with a Medicare contractor's [LMRP] could not be false as a matter of law because . . . LMRPs do not establish 'controlling' standards." (D.E. 57 at 14, citing *Prabhu*, 442 F. Supp. 2d 1032-33). Defendant's one word quotation, however, omits salient facts which limit and condition the *Prabhu* court's holding. As the paragraph cited by Defendants in *Prahbu* readily sets forth, the LMRP which the Government alleged had been violated was not "controlling" because it applied only to services provided in California, and not in Nevada, where the provider was based and had submitted claims for payment, a fact acknowledged by the Government's expert. *See Prabhu*, at 1032. Defendants seize on a single word quote to wrongly suggest that "LMRPs do not establish 'controlling' standards." (D.E. 57 at 14, citing *Prabhu*, 442 F. Supp. 2d 1032-33). The *Prabhu*

court's decision was merely based on the narrow factual issue of whether a LMRP covering the state of California could govern the actions of a provider in Nevada. Contrary to Defendant's assertions, Prabhu does not stand for the overarching proposition that LMRPs and/or LCDs cannot establish controlling standards which could form the basis of an FCA cause of action.

Indeed, Defendant's sweeping interpretation of MedQuest and Prabhu could lead to absurd results. For example, a Medicare provider could be required to follow certain requirements in an LCD when providing a service. That LCD could further state that if the services were provided outside of those guidelines they would not be considered "reasonable and necessary," which is a requirement for payment under Medicare's regulations. Under Defendant's formulation, an entity could simply ignore those requirements and knowingly submit claims to Medicare for services that entity knows Medicare has stated it does not consider reasonable and necessary and will not be reimbursed. Despite this knowing submission of improper, and very likely false claims, Medicare would nonetheless be required to pay for the service and the entity would have no FCA liability. Such a result cannot have been the intention of the panel in *MedQuest* or the court in *Prabhu*.

II. An FCA Complaint Need Not Identify Specific Claims for Reimbursement to Meet Rule 9(b) When Alleging That All Claims of a Particular Type are False and When Claims Information is Within **Defendant's Control**

Defendant argues that Relator's Complaint must be dismissed because, among other reasons, Relator does not identify any specific false claims for reimbursement to the United States or identify how any particular claim was false or fraudulent. See D.E. 57 at 15 – 18. Though the Sixth Circuit traditionally requires the pleading of an actual false claim with particularity under Rule 9(b), it has also stated that this rule may be relaxed under certain circumstances. E.g., United States ex rel. Bledsoe v. Cmty. Health Sys., Inc., 501 F.3d 493, 504

n.12 (6th Cir. 2007) ("Bledsoe II"). The purpose of Rule 9(b) "is not to reintroduce formalities to pleading, but is instead to provide defendants with a more specific form of notice as to the particulars of their alleged misconduct." Id. at 503. Thus, Rule 9(b) must be interpreted in harmony with Rule 8, which requires that a complaint provide "a short and plain statement of the claim" made by "simple, concise, and direct allegations." Id. (quoting Fed. R. Civ. P. 8(a)). Under Rule 8, a complaint need not allege an exhaustive roadmap of a plaintiff's claims, but must be sufficient to "give the defendant fair notice of what the...claim is and the grounds upon which it rests." Erickson v. Pardus, 551 U.S. 89, 93 (2007) (quoting Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007)).

In order to strike a balance between Rule 9(b) and Rule 8, the Court may relax Rule 9(b)'s requirement of identifying specific false claims when Relator details the fraudulent scheme and alleges that all claims submitted related to that specific type of fraudulent conduct were false. See U.S. ex rel. Poteet v. Medtronic, Inc., 552 F.3d 503, 518 (6th Cir. 2009) (holding that Relator's detailed allegations of fraudulent scheme and individuals involved was "more than sufficient to enable the named defendants to prepare a responsive pleading to the charges presented.")

Courts have also relaxed the requirement that Relator identify specific false claims when such information is presumably exclusively within Defendant's control. In these situations, courts have looked to whether the plaintiff has provided enough detail to permit the defendant to "fashion a responsive pleading addressing her claims." United States ex rel. Lane v. Murfreesboro Dermatology Clinic, PLC, No. 4:07-cv-4, 2010 WL 1926131, at *6-7 (E.D. Tenn. May 12, 2010); United States ex rel. Villafane v. Solinger, 457 F. Supp. 2d 743, 755 (W.D. Ky. 2006).5

III. Conclusion

Defendants are incorrect in their blanket assertion that LCDs cannot form the basis of a FCA cause of action. In addition, the heightened pleading requirements of Rule 9(b) may be relaxed in certain situations in pleading an FCA cause of action. As such, The United States respectfully requests that the Court consider this Statement of Interest as it interprets the FCA with regard to Defendant's Motion to Dismiss.

Respectfully submitted,

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⁵ Similarly, Rule 9(b) does not require a plaintiff to plead the identity of the specific employees within a defendant corporation who submitted false claims to the United States. Bledsoe II, 501 F.3d at 506. Such a standard "is not required by the FCA itself or the text of Rule 9(b), nor is it required by . . . binding precedents." Id. The Court may consider the presence of such allegations as "relevant to the inquiry of whether a relator has pled the circumstances constituting fraud with particularity," but such details are not required to meet the Rule 9(b) threshold. Id. at 509.

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing Notice was filed with the Court's ECF system on October 11, 2013, and delivered electronically via operation thereof to the following:

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